4.7 SUMMARY OF SAFETY AND EFFECTIVENESS

510(K) SUMMARY

Date Prepared

April 23, 2001

Submitter's Information

Walter Weyburne Hitachi Medical Corporation of America 660 White Plains Road Tarrytown, NY 10591 (914) 524-9711

Joseph M. Azury III Azary Technologies LLC PO Box 2156 Huntington, CT 06484 (203) 944-9320

Trade Name, Common Name, Classification

The device trade names are:

- EUB-6000 Ultrasound system
- SP-711UA
- SP-711 Sonoprobe system

Predicate Device

The EUB-6000 was previously cleared by the FDA under 510(k) K994026. The predicate device for the Fujinon SP-711 Sonoprobe system is the Fujinon Endoscopically Deliverable Ultrasound Point Probe System (SP-701), which received FDA marketing clearance on 12/12/97 under accession number K971528.

Description of the Device

The subject device consists of:

- EUB-6000 Diagnostic Ultrasound Scanner
- SP-711UA Ultrasonic Probe Connecting Unit
- TL-1A Translator
- Probe (PL Series or PL26-7.5 Series)
- · Balloon and Sheath

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The subject device consists of two separate assemblies. The Hitachi EUB-6000 Diagnostic Ultrasound Scanner and the Fujinon SP711 Sonoprobe system. The Fujinon SP711 Sonoprobe system is an optional add-on device for the Hitachi EUB-6000 which allows the EUB-6000 to utilize the Fujinon probes.

The Hitachi EUB-6000 Diagnostic Ultrasound Scanner has previously been cleared by the FDA under 510(k) K994026. The Fujinon SP711 Sonoprobe system has as a predicate device the Fujinon SP-701 Sonoprobe system which has been cleared by the FDA under 510(k) K971528.

The Hitachi EUB-6000 operating controls and their associated functions do not change with the addition of the Fujinon SP-711 Sonoprobe system. The operating controls specific to the Fujinon SP-711 system are described in the operation manuals included with this document in Section 7.

The transducers subject to this submission are the same transducers described in the predicate 510(k) K971528. The only exception is the addition of the PL2220 series and the PL26-7.5 series (which includes a 7.5MHz probe). The tips of the PL26-7.5 series probes have a different shape compared to the PL series probes. A diagram and chart comparing the differences between the probes can be found in Section 4.5. This submission includes the following transducers:

PL1726-20	PL1726-15	PL1726-12	PL1726-7.5
PL1926-20	PL1926-15	PL1926-12	PL1926-7.5
PL2226-20	PL2226-15	PL2226-12	PL2226-7.5
PL2220-20	PL2220-15	PL2220-12	

The PL26-7.5 probe series includes one type for use with a balloon/sheath and the other type for use without a balloon. The only difference between probes is the structure of the tip. The probes made for use with a balloon/sheath have a groove on the tip to catch the balloon head. The probes made for use without a balloon are slightly shorter. The choice of the probe type is at the discretion of the physician. Since ultrasound waves are stronger in water, the physician may choose to use the balloon version to improve image quality. The probes made for use with a balloon/sheath are designated with a "B" (i.e. PL26B-7.5) and must be used with a balloon adapter, balloon sheath, and balloon as described in the operation manual.

Intended Use

The intended use of the subject device is for endoscopic observation of the gastrointestinal tract (esophagus, stomach, duodenum, large intestine) and biliary system (pancreato-biliary ducts). The Ultrasound Device Indications Statements for each application and mode of the system/transducers are included with this document.

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Technological Characteristics

The transducers and translator used with the subject device are composed of the same materials as the predicate device. The biocompatibility data on those materials were submitted in a previous 510(k). The subject device is not life sustaining and does not control any life sustaining devices. The images are interpreted by a physician, providing ample opportunity for competent human intervertion.

The SP-711 scans radially only and does not offer a linear scanning option as the predicate device does. The transducers subject to this submission are the same as the predicate device, with the exception of the addition of the following transducers:

- PL26-7.5 series produces an ultrasonic frequency of 7.5MHz and has a distal end diameter of 7.3mm.
- PL2220 series with a diameter of 2.0mm to be used to visualize the biliary system (pancreato-biliary ducts).

The translator in the subject device is identical to the translator found in the predicate device with the exception of a minor change in shape to facilitate cleaning and disinfection.

The subject device has the identical thermal, mechanical, and electrical safety features as found in the predicate device.

Performance Data

The subject device conforms to IEC 60601-1 standard, Medical Electrical Equipment – Part 1: General Requirements for Safety.

The measurements of the acoustic intensities of the probes for the SP-711 are well below the pre-amendment upper limits. The probes were subjected to Failure Mode Criticality Analysis for two types of failures; over voltage applied to the transducer, and change in pulse repetition rate. The probes have a Thermal Index (TI) of less than one, meaning the surface heating of the probes would not present a danger to the patient in the event of a malfunction.

Conclusion

We conclude that the subject device is as safe and effective as the predicate device.



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

MAY 3 0 2001

Mr. Walter Weyburne Hitachi Medical Corporation of America 660 White Plains Road TARRYTOWN NY 10591-5107

Re: K011252

Trade Name: EUB-6000 Diagnostic Ultrasound Scanner with Fujinon SP711UA/SP711 Sonoprobe System

Regulatory Class: II/21 CFR 892.1560

Product Code: 90 IYO Dated: April 23, 2001 Received: April 24, 2001

Dear Mr. Weyburne:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Hitachi EUB-6000 Diagnostic Ultrasound Scanner, as described in your premarket notification:

Transducer Model Number
PL1726-20
PL1726-15
PL1726-12
PL1726-7.5
PL1926-20
PL1926-15
PL1926-12
PL1926-7.5
PL2226-20
PL2226-15

PL2226-12 PL2226-7.5 PL2220-20 PL2220-15 PL2220-12

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at

(301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

System/Transducer: EUB-6000 System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Diagnostic ultrasound imagination						Operation		
General	Specific	В	M	PWD	CWD	Color	Amplitude	Combined*	Other**
(Track 1 only)	•		İ			Doppler	Doppler	(specify)	(specify)
Ophthalmic	Ophthalmic								
	Fetal	Ρ.	P	P	Р	P	Р	Р	Р
	Abdominal	Pa	Pa	Pa	Pa	Pa	Pa	Pa	Pa
1	Intraoperative (specify)	Pb	Pb	Pb		Pb	Pb	Pb	Pb
	Intraoperative (Neuro.)	Р	P	P		P	Р	P	Р
	Laparoscopic	Р	Р	P		Р	Р	Р	P
	Pediatric	Р	Р	Р	Р	Р	Р	Р	P
	Small Organ (specify)	Р	P	Р		Р	Р	Р	Р
	Neonatal Cephalic	Р	Р	Р		Р	Р	Р	Ρ
Catal tona aim a	Adult Cephalic	P	P	Р	Р	Р	Р	P	P
Fetal Imaging & Others	Trans-rectal	Ph	Ph	Ph		<u>Ph</u>	Ph	Ph	Ph
a Others	Trans-vaginal	Pf_	Pf	Pf		Pf	Pf	Pf	Pf
	Trans-urethral								
	Trans-esophageal								
	Muskulo-skeletal	Р	P	Р		Р	P	P	Р
	Conventional								
	Musculo-skeletal	P	lр	Р		P	Р	P	Р
	Superficial		ļ						
	Intra-luminal	Ni		ļ					
	Other (specify)							Р	Р
	Cardiac Adult	P	P	Р	P	<u>Р</u> Р	P P	P	P
	Cardiac Pediatric	Р	Р	Р	P	P	Р	<u>_</u>	
Cardiac	Cardiac Transesophageal Adult	Р	Р	Р		Р	Р	Р	Р
	Cardiac Transesophageal Pediatric	P	Р	Р		Р	Р	Р	Р.
	Other (specify)								
Peripheral	Peripheral Vascular	Р	Р	Р	Р	Р	Р	Р	Р
Vessel	Other (specify)						day against		

N=new indication; P=previously cleared by FDA under 510(k)# K994026; E=added under appendix E

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures)

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy

Subscript "e": Includes imaging for guidance of transrectal biopsy.

Subscript "f": Includes imaging for guidance of tranvaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of transrectal biopsy, cryosurgery, and brachytherapy.

Subscript "i": Includes imaging of the biliary system (pancreato-biliary) and gastrointestinal tract (esophagus, stomach, duodenum, and

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, And Radiological Devices

^{*}Combination of each operating mode, B, M, PWD, CWD, and Color Doppler

^{**}Amplitude Doppler and Harmonic Imaging

Diagnostic Ultrasound Indications for Use Form

General Specific (Tracks & III) Ophthalmic Ophthalmic Ophthalmic		Diagnostic ultrasound imagir	19 01 11		22.,0		Mode of	Operation		
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510(k) Number: <u>K011252</u>

Cli	Diagnostic ultrasound imagii nical Application	Ī				Mode of	Operation		
General	Specific	В	М	PWD	CWD	Color	Amplitude	Combined*	Other**
(Track 1 only)			ŀ			Doppler	Doppler	(specify)	(specify)
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intraoperative (specify)								
	Intraoperative (Neuro.)								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)		<u> </u>	ļ					
	Neonatal Cephalic		<u> </u>	ļ					
Fetal Imaging	Adult Cephalic		ļ	ļ					
& Others	Trans-rectal		ļ						
a outlot	Trans-vaginal		ļ				ļ		
	Trans-urethral		ļ						
	Trans-esophageal		ļ	ļ			ļ		
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Cardiac	Adult		İ				İ .		
Cardiac	Cardiac Transesophageal								
	Pediatric			1.					
	Other (specify)								
Peripheral	Peripheral Vascular								
Vessel	Other (specify)								
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la	arge intestine).			14/71/10/1	115 00	UTINUE ON ANOT	NED DACE IE NEI	DED)	
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System/Transducer: PL1726-12

Diagnostic Ultrasound Indications for Use Form

	Diagnostic ultrasound imagir nical Application	ľ				Mode of	Operation		
General	Specific	В	M	PWD	CWD	Color	Amplitude	Combined*	Other**
(Track 1 only)		-				Doppler	Doppler	(specify)	(specify)
Ophthalmic	Ophthalmic								
Органалия	Fetal								
	Abdominal		1						
	Intraoperative (specify)								
	Intraoperative (Neuro.)								
	Laparoscopic		-						
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
Fetal Imaging	Trans-rectal								
& Others	Trans-vaginal								
	Trans-urethral								
	Trans-esophageal								
	Muskulo-skeletal								
	Conventional			1					
	Musculo-skeletal	, , , , ,							
	Superficial	L							
	Intra-luminal	Pi							
	Other (specify)								
	Cardiac Adult								
Cardiac	Cardiac Pediatric								
	Cardiac Transesophageal								
	Adult								
	Cardiac Transesophageal							l i	
	Pediatric								·
	Other (specify)								
Peripheral	Peripheral Vascular								
Vessel	Other (specify)								
Combination o *Amplitude Do	on; P=previously cleared by if each operating mode, B, N ppler and Harmonic Imaging ments:	1, PWC)), CWD	, and C	olor Dop	opler			
Subscript "a": Ir	actudes imaging for guidance	e of pe	rcutane	ous bio	psy of a	ibdominal org	ans and struct	ures (including	amniocentes
Subscript "b": Ir	ncludes imaging of organs a	nd stru	ctures	exposed	d during	surgery (exc	luding neurosu	rgery and lapa	roscopic pro
Subscript "c": Ir	ncludes thyroid, parathyroid.	breast	. scrotu	ım, peni	is.				
Subscript "d": Ir	ncludes thyroid, parathyroid,	breast	, scrotu	ım, pen	is and ir	naging for gu	idance of biops	sy.	
Subscript "e": Ir	ncludes imaging for guidance	e of tra	nsrecta	d biopsy	<i>ı</i>				
Subscript "f": Ir	ncludes imaging for guidance	e of tra	nvagin	al biops	у.				
Subscript "a": F	or pediatric patients.								
Subscript "h" Ir	actudes imaging for guidance	e of tra	nsrecta	l biopsy	, cryosi	urgery, and bi	achytherapy.		
Subscript "i": Ir	ncludes imaging of the biliary	/ syste	m (pan	creato-b	oiliary) a	nd gastrointe	stinal tract (esc	ophagus, stom	ach, duodeni
la	arge intestine)								
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			And	Radiole	ogical D	evices			

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	Diagnostic ultrasound imagir nical Application					Mode of	Operation		
General	Specific	В	M	PWD	CWD	Color	Amplitude	Combined*	Other**
Frack 1 only)						Doppler	Doppler	(specify)	(specify)
Ophthalmic	Ophthalmic								
O P.11.10.11.10	Fetal								
	Abdominal								
	Intraoperative (specify)								
•	Intraoperative (Neuro.)								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								· ·
	Neonatal Cephalic								
atal Impanian	Adult Cephalic								
etal Imaging & Others	Trans-rectal								
a Officis	Trans-vaginal			L					
	Trans-urethral			<u> </u>					
	Trans-esophageal								
	Muskulo-skeletal]	1
	Conventional			ļ					
	Musculo-skeletal								l
	Superficial			ļ					
	Intra-luminal	_Ei_					 		
	Other (specify)								
	Cardiac Adult			ļ					
	Cardiac Pediatric								
	Cardiac Transesophageal								
Cardiac	Adult								
	Cardiac Transesophageal]					
	Pediatric						<u> </u>		
5	Other (specify)								
Peripheral	Peripheral Vascular								
Vessel	Other (specify)		-d 54	0(14)# 16	071520	· E-addod ur	dar appondix F	<u> </u>	
-new indication	on; P=previously cleared by	FDA U	ager 5 i	U(K)# N	97 1520 Nor Dor	, c=auueu u⊩	idei appendix i	=	
ombination o	f each operating mode, B, N	I, PVVL	, CVVD	, and C	DIOI DO	phiei			
Amplitude Do Iditional Com	ppler and Harmonic Imaging	1							
ibecrint "a": Ir	ncludes imaging for guidance	of ne	rcutane	ous bio	osv of a	bdominal org	ans and struct	ures (including	amniocentesis)
ibscript "h": Ir	ncludes imaging of organs a	nd stru	ctures e	exposed	durino	surgery (exc	udina neurosu	rgery and lapar	oscopic proced
bscript "c": Ir	ncludes thyroid, parathyroid,	breast	scrotu	m. pen	s.	9 1			
bscript "d": Ir	ncludes thyroid, parathyroid,	breast	scrotu	m. pen	s and in	naging for qui	idance of biops	٧٠.	
bscript "e": Ir	ncludes imaging for guidance	of tra	nsrecta	biopsy					
bscript "f": Ir	ncludes imaging for guidance	of tra	nvagina	al biops	٧.				
bscript "a". F	or pediatric patients.	3 01 110	ivagiii	<u></u>					
ibscript "b": Ir	ncludes imaging for guidance	of tra	nsrecta	l bioosy	. crvosı	irgery, and br	achytherapy.		
bscript "i" tr	ncludes imaging of the biliary	syste	n (pano	creato-t	iliary) a	nd gastrointe	stinal tract (esc	phagus, stoma	ch, duodenum
	rge intestine)								
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	Diagnostic ultrasound imagir nical Application	1					Operation	-	
General	Specific	В	M	PWD	CWD	Color	Amplitude	Combined*	Other**
(Track 1 only)		_	1			Doppler	Doppler	(specify)	(specify)
Ophthalmic	Ophthalmic		1	1					
<u> </u>	Fetal		1	1					
	Abdominal			1					
	Intraoperative (specify)		<u> </u>						
	Intraoperative (Neuro.)								
	Laparoscopic		1						
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
etal Imaging & Others	Trans-rectal								
& Others	Trans-vaginal								
	Trans-urethral								
	Trans-esophageal								
	Muskulo-skeletal								
	Conventional		ļ						
	Musculo-skeletal								
	Superficial						-		
	Intra-luminal	Pi	ļ						
	Other (specify)								
	Cardiac Adult		ļ						
	Cardiac Pediatric								
	Cardiac Transesophageal				i				
Cardiac	Adult		<u></u>	 					
	Cardiac Transesophageal				1			·	
	Pediatric		-						
B 11 1	Other (specify)			 					
Peripheral	Peripheral Vascular								
Vessel	Other (specify)			0/1-24/16	074 500	. F. addad ua	dar annandiy [
=new indication	on; P=previously cleared by	FDA U	nder 51	U(K)# K	9/1528	; E=adoed un	der appendix i	=	
	of each operating mode, B, M		, CWD	, and Co	JIOI DOL	phiei			
ditional Com	ppler and Harmonic Imaging	l							
ubscrint "a": It	ncludes imaging for guidance	of ne	rcutane	ous bio	nsv of a	bdominat orga	ans and struct	ures (includina	amniocentesis
ubscript "h": Ir	ncludes imaging of organs ar	nd stru	ctures e	exposed	durina	surgery (excl	udina neurosu	rgery and lapar	oscopic proce
ubscript "c"- Ir	ncludes thyroid, parathyroid,	breast	scrotu	m neni	S.	3		3 1	
ubscript "d": Ir	ncludes thyroid, parathyroid,	breast	scrotu	m peni	s and ir	naging for gui	dance of biops	V.	
ubscript "e": Ir	ncludes imaging for guidance	of trai	nsrecta	biopsy					-
	ncludes imaging for guidance								
	or pediatric patients.	3 01 114	···ag	0.000					
ubscript "h": Ir	ncludes imaging for guidance	of trai	nsrecta	Lbionsy	Cryosi	rgery, and bra	achytherapy.		
ubscript "i": Ir	ncludes imaging of the biliary	syster	n (pano	creato-b	iliary) a	nd gastrointes	stinal tract (esc	phagus, stoma	ch, duodenun
	arge intestine).	Cyclo	ii (paii					· · · · · · · · · · · · · · · · · · ·	,
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System/Transducer: PL1926-15

Diagnostic Ultrasound Indications for Use Form

	Diagnostic ultrasound imagi nical Application	Ĭ					Operation		
General	Specific	В	М	PWD	CWD	Color	Amplitude	Combined*	Other**
(Track 1 only)	(Tracks & III)					Doppler	Doppler	(specify)	(specify)
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intraoperative (specify)								
	Intraoperative (Neuro.)			·					
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic		1						
	Adult Cephalic								
etal Imaging	Trans-rectal	l							
& Others	Trans-vaginal		ļ						
	Trans-urethral			İ					
	Trans-esophageal		T						
ł	Muskulo-skeletal								
	Conventional								
	Musculo-skeletal								
	Superficial			1			1		
İ	Intra-luminal	Pi							
	Other (specify)								
	Cardiac Adult								
•	Cardiac Pediatric								-
t	Cardiac Transesophageal								
Cardiac	Adult								
	Cardiac Transesophageal								
	Pediatric								
	Other (specify)								
Peripheral	Peripheral Vascular								
Vessel	Other (specify)								
=new indicatio	n; P=previously cleared by	FDA u	nder 51	0(k)# K	971528	E=added un	der appendix E		
Combination of	each operating mode, B, M	1, PWD	, CWD	and Co	olor Dop	pler			
	opler and Harmonic Imaging								
dditional Com	ments:								
ubscript "a": In	cludes imaging for guidance	e of per	rcutane	ous bio	osy of a	bdominal org	ans and structi	res (including	amniocentesis).
ubscript "b": In	cludes imaging of organs a	nd stru	ctures e	exposed	during	surgery (excl	uding neurosu	gery and lapar	oscopic procedu
ubscript "c": In	cludes thyroid, parathyroid,	breast	, scrotu	m, peni	S				
ubscript "d": In	cludes thyroid, parathyroid,	breast	, scrotu	m, peni	s and in	naging for gui	dance of biops	у.	
	cludes imaging for guidance								
	cludes imaging for guidance	of tra	nvagina	l biopsy	/				
ubscript "g": Fo	or pediatric patients.								
ubscript "h": In	cludes imaging for guidance	of trai	nsrecta	l biopsy	, cryosu	rgery, and br	achytherapy.		
ubscript "i": In	cludes imaging of the biliary	syster	n (pand	reato-b	iliary) a	nd gastrointes	stinal tract (esc	phagus, stoma	ich, duodenum, a
la	rge intestine).								
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Diagnostic Ultrasound Indications for Use Form

	Diagnostic ultrasound imagii nical Application	ľ					Operation		
General	Specific	В	M	PWD	CWD	Color	Amplitude	Combined*	Other**
(Track 1 only)	(Tracks I & III)					Doppler	Doppler	(specify)	(specify)
Ophthalmic	Ophthalmic								
	Fetal					-			
	Abdominal								
	Intraoperative (specify)								
	Intraoperative (Neuro.)		1						
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic		1						
5 - 1 - 1 1 1	Adult Cephalic								
Fetal Imaging	Trans-rectal								
& Others	Trans-vaginal								
	Trans-urethral								
	Trans-esophageal								
	Muskulo-skeletal							İ	l
	Conventional								
	Musculo-skeletal								
	Superficial								
	Intra-luminal	Pi							
	Other (specify)								
	Cardiac Adult								
	Cardiac Pediatric								
Cardiac	Cardiac Transesophageal Adult								
	Cardiac Transesophageal Pediatric				-				
	Other (specify)								
Peripheral	Peripheral Vascular								
Vessel	Other (specify)								
=new indication	on; P=previously cleared by	FDA u	nder 51	0(k)# K	971528	E=added un	der appendix E	•	
Combination o	f each operating mode, B, M	I, PWC	, CWD	, and Co	olor Dop	pler			
*Amplitude Do	ppler and Harmonic Imaging								
dditional Com	ments:								
ubscript "a": Ir	cludes imaging for guidance	e of pe	rcutane	ous bio	osy of a	bdominal orga	ans and structi	ures (including	amniocentesis)
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ubscript "c": Ir	cludes thyroid, parathyroid,	breast	, scrotu	m, peni	s.				
	cludes thyroid, parathyroid,					naging for gui	dance of biops	у.	
ubscript "e": Ir	cludes imaging for guidance	of tra	nsrecta	biopsy					
	cludes imaging for guidance	of tra	nvagina	al biopsy	/.				
	or pediatric patients.								
ubscript "h": In	cludes imaging for guidance	of tra	nsrecta	I biopsy	, cryosu	rgery, and br	acnytherapy.		
	cludes imaging of the biliary	syster	n (pan	creato-b	iliary) ai	nd gastrointes	stinal tract (esc	phagus, stoma	ch, duodenum
la	rge intestine).	OT WO	TE 0510	W TUIC !!	NE CO	TINUE ON ANOT	HER PAGE IF NEE	DED)	
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And Radiological Devices

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	Diagnostic ultrasound imagir	g or flu	uid flow	analys	is of the	numan body	Operation		
Clir	nical Application			1000	CWD	Color	Operation Amplitude	Combined*	Other**
General	Specific	В	M	PWU	CWD	Doppier	Doppler	(specify)	(specify)
Track 1 only)	(Tracks I & III)			 		Соррісі	Сорры	1 1000000	
Ophthalmic	Ophthalmic		ļ						
	Fetal			 			1	T	
	Abdominal		 						
	Intraoperative (specify) Intraoperative (Neuro.)		 	 -					
	Laparoscopic								
	Pediatric		 						
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etal Imaging	Trans-rectal								
& Others	Trans-vaginal		1	1					
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	Muskulo-skeletal			1					
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	Musculo-skeletal			1					
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	Other (specify)		 	 			 		
Peripheral	Peripheral Vascular						 		
Vessel	Other (specify)		1	10(1)# 1	071520	. E-added u	nder appendix	F	
l=new indication	on; P=previously cleared by	FDA U	LIGEL 2	iu(k)# n	olor Do	nnler	idel appendix	-	
Combination of	of each operating mode, B, N	N, PVVL), CVVL	, and O	000 00	ppiei			
dditional Cam	ppler and Harmonic Imaging								
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Subscript "d": I	ncludes thyroid, parathyroid,	breas	t, scroti	ım, pen	is and i	maging for gu	ridance of biop	sy.	
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ubscript "a". F	or pediatric patients.								
ubcorint "h" - le	ncludes imaging for quidance	e of tra	insrecta	al biops	y, cryos	urgery, and b	rachytherapy.		
Subscript "i": I	ncludes imaging of the biliar	y syste	m (pan	creato-l	biliary) a	and gastrointe	estinal tract (es	ophagus, stom	ach, duodenum
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Track 1 only) (Tracks I & III) Doppler Doppler (specify) Ophthalmic Ophthalmic Fetal Abdominal Intraoperative (specify) Intraoperative (specify) Intraoperative (Neuro.) Laparoscopic Pediatric Small Organ (specify) Neonatal Cephalic Adult Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-vershral Trans-vaginal Trans-vershra	Other**
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Abdominal Intraoperative (specify) Intraoperative (Neuro.) Laparoscopic Pediatric Small Organ (specify) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-uethral Trans-esophageal Muskulo-skeletal Conventional Musculo-skeletal Superficial Intra-tuminal Other (specify) Cardiac Adult Cardiac Trans-sophageal Adult Cardiac Trans-sophageal Adult Cardiac Trans-sophageal Adult Cardiac Trans-sophageal Adult Cardiac Trans-sophageal Adult Cardiac Trans-sophageal Adult Cardiac Trans-sophageal Adult Cardiac Trans-sophageal Adult Cardiac Trans-sophageal Adult Cardiac Trans-sophageal Adult Cardiac Trans-sophageal Adult Cardiac Trans-sophageal Adult Cardiac Trans-sophageal Adult Cardiac Trans-sophageal Adult Cardiac Trans-sophageal Adult Cardiac Trans-sophageal Adult Cardiac Trans-sophageal Adult Cardiac Trans-sophageal Pediatric Other (specify) Peripheral Vessel Other (specify) Peripheral Vessel Other (specify) Trans-rectal biopsy of abdominal organs and structures (including ubscript "to-": includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including ubscript "to-": includes imaging of organs and structures exposed during surgery (excluding neurosurgery and lapa ubscript "to-": includes imaging of organs and structures exposed during surgery (excluding neurosurgery and lapa ubscript "to-": includes imaging for guidance of transrectal biopsy. ubscript "to-": includes imaging for guidance of transrectal biopsy, cyrosurgery, and brachytherapy. ubscript "godes imaging for guidance of transrectal biopsy, cyrosurgery, and brachytherapy. ubscript "godes imaging for guidance of transrectal biopsy, cyrosurgery, and brachytherapy. ubscript "godes imaging for guidance of transrectal biopsy, cyrosurgery, and brachytherapy. ubscript "godes imaging for guidance of transrectal biopsy, cyrosurgery, and brachytherapy. ubscript "godes imaging for guidance of transrectal biopsy, cyrosurgery, and brachytherapy. ubscript "godes imaging for guidance of transrectal biopsy, cyrosurgery	
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abscript "c": Includes thyroid, parathyroid, breast, scrotum, penis. abscript "d": Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy. abscript "e": Includes imaging for guidance of transrectal biopsy. abscript "f": Includes imaging for guidance of transrectal biopsy. abscript "g": For pediatric patients. abscript "h": Includes imaging for guidance of transrectal biopsy, cryosurgery, and brachytherapy. abscript "i": Includes imaging of the biliary system (pancreato-biliary) and gastrointestinal tract (esophagus, stomatarge intestine).	osconic procec
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ubscript "f": Includes imaging for guidance of tranvaginal biopsy. ubscript "g": For pediatric patients. ubscript "h": Includes imaging for guidance of transrectal biopsy, cryosurgery, and brachytherapy. ubscript "i": Includes imaging of the biliary system (pancreato-biliary) and gastrointestinal tract (esophagus, stomagregiontestine). (PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)	
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ubscript "h": Includes imaging for guidance of transrectal biopsy, cryosurgery, and brachytherapy. ubscript "i": Includes imaging of the biliary system (pancreato-biliary) and gastrointestinal tract (esophagus, stomatarge intestine). (PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)	
ubscript "i": Includes imaging of the biliary system (pancreato-biliary) and gastrointestinal tract (esophagus, stomating intestine). (PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)	
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large intestine). (PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)	ich, duodenum.
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(Division sign-Off)	
Division of Reproductive, Abdominal, ENT,	
And Radiological Devices	

	Diagnostic ultrasound imagir	ng or th	uid flow	analys	IS OI THE	numan bouy	On andia					
	nical Application	Mode of Operation B M PWD CWD Color Amplitude Combined* Other**										
General	Specific	В	M	PWD	CWD				(specify)			
(Track 1 only)			 			Doppler	Doppler	(specify)	(specity)			
Ophthalmic	Ophthalmic		ļ				 	-				
·	Fetal		ļ.—	ļ				ļ				
	Abdominal						 					
	Intraoperative (specify)	<u> </u>	ļ				ļ					
	Intraoperative (Neuro.)		ļ				-					
	Laparoscopic		 									
	Pediatric		ļ				 					
	Small Organ (specify)		ļ	 								
	Neonatal Cephalic		 	 								
Fetal Imaging	Adult Cephalic		ļ									
& Others	Trans-rectal		ļ									
	Trans-vaginal		<u> </u>	ļ			 					
	Trans-urethral		ļ	ļ			 					
	Trans-esophageal		 	 			 					
	Muskulo-skeletal		1						1			
	Conventional		 				 					
	Musculo-skeletal							[
	Superficial	Pi	 									
	Intra-luminal	PI	 	1			 					
	Other (specify)		ļ									
	Cardiac Adult						 					
	Cardiac Pediatric		ļ				-					
0	Cardiac Transesophageal											
Cardiac	Adult			ļ								
	Cardiac Transesophageal								ı			
	Pediatric Other (appoint)											
Devisional	Other (specify)											
Peripheral	Peripheral Vascular		 									
Vessel	Other (specify)			0/12# 16	071500	. E. oddod un	dar sanandiy (<u> </u>				
=new indication	on; P=previously cleared by f each operating mode, B, M	FDA U	naer 5 i	U(K)# K	97 1520 Nor Do	nder	idei appelidix i	<u>-</u>				
			, CVVD	, and O	וסם וטונ	phici						
dditional Com	ppler and Harmonic Imaging	I										
Subscript "a": Ir	ncludes imaging for guidance	of ne	rcutane	ous bio	nsv of a	bdominal org	ans and structi	ures (includina	amniocentesis			
Subscript "h": Ir	ncludes imaging of organs at	nd stru	ctures e	exposed	during	surgery (exc	udina neurosu	rgery and lapar	roscopic proced			
ubscript "c": Ir	ncludes thyroid, parathyroid,	breast	scrotu	m neni	S.		3					
ubscript "d": Ir	ncludes thyroid, parathyroid,	breast	scrotu	m peni	s and ir	naging for gu	idance of biops	SV.				
ubscript "a": Ir	ncludes imaging for guidance	of tra	nsrecta	l bionsy		-3 3 - 3		<u> </u>				
ubscript "f" Ir	ncludes imaging for guidance	of tra	nvanina	al hionsy	<u>. </u>							
	or pediatric patients.	or tra	ivagine	ai biopo	<u>. </u>			****				
ubscript "b": Ir	ncludes imaging for guidance	of tra	nsrecta	Lhionsy	cryosi	irgery, and br	achytherapy.					
ubscript "i" - Ir	ncludes imaging of the biliary	eveto	m (nano	reato-h	ilian/) a	nd gastrointe	stinal tract (esc	ophagus, stoma	ach, duodenum			
	arge intestine).	System	п (рап	orouto b		no gaotromio	Julia 11 apr (550	pringer, crew	,			
	(PLEASE DO N	IN TO	TE BELO	W THIS LI	NE - CO	TINUE ON ANO	THER PAGE IF NEI	EDED)				
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System/Transducer: PL2226-12

Diagnostic Ultrasound Indications for Use Form

Clir	nical Application	ing or fluid flow analysis of the human body as follows: Mode of Operation									
General	Specific	В	M	PWD	CWD	Color	Amplitude	Combined*	Other**		
(Track 1 only)						Doppler	Doppler	(specify)	(specify)		
Ophthalmic	Ophthalmic										
Оринанис	Fetal			 							
	Abdominal			1							
				1							
	Intraoperative (specify)			1							
	Intraoperative (Neuro.)		 								
	Laparoscopic			 							
	Pediatric		 	 							
	Small Organ (specify)						1				
	Neonatal Cephalic			 							
Fetal Imaging	Adult Cephalic		ļ	 			-				
& Others	Trans-rectal						·				
	Trans-vaginal		<u> </u>	 			 				
	Trans-urethral		ļ	<u> </u>							
	Trans-esophageal			 				 			
	Muskulo-skeletal										
	Conventional	:		 							
	Musculo-skeletal							. [j		
	Superficial			 							
	Intra-luminal	Pi		<u> </u>			 				
	Other (specify)						<u> </u>				
	Cardiac Adult			<u> </u>							
	Cardiac Pediatric			ļ							
	Cardiac Transesophageal										
Cardiac	Adult			ļ							
·	Cardiac Transesophageal								ľ		
	Pediatric						ļ				
	Other (specify)										
Peripheral	Peripheral Vascular										
Vessel	Other (specify)							<u> </u>			
V=new indication	on; P=previously cleared by	FDA u	nder 5	10(k)# K	971528	l; E=added ur	nder appendix i	E			
Combination o	f each operating mode, B, N	I, PWE), CWD), and C	olor Do	ppler					
*Amplitude Do	ppler and Harmonic Imaging)									
Additional Com	ments:							Construction			
Subscript "a": Ir	ncludes imaging for guidance	e of pe	rcutane	eous bio	psy of a	abdominal org	ans and struct	ures (including	amniocentesis		
Subscript "b": Ir	ncludes imaging of organs a	nd stru	ctures	exposed	d during	surgery (exc	luding neurosu	irgery and lapa	roscopic proced		
Subscript "c"- Ir	ncludes thuroid narathyroid	breast	scrote	ım. pen	is.						
Subscript "d": Ir	ncludes thyroid, parathyroid,	breast	, scroti	ım, pen	is and i	maging for gu	idance of biop:	sy			
Subscript "e": Ir	ncludes imaging for guidance	e of tra	nsrecta	al biopsy	<i>l:</i>						
Subscript "f": Ir	ncludes imaging for guidance	e of tra	nvagin	al biops	y						
Subscript "a": F	or pediatric patients.										
Subcorint "b": Ir	soludos imagina for quidance	e of tra	nsrecta	al biopsy	, cryos	urgery, and b	rachytherapy.				
Subscript "i": Ir	ncludes imaging for guidance	ysyste	m (pan	creato-l	oiliary) a	and gastrointe	stinal tract (es	ophagus, stoma	ach, duodenum		
	erao intactino)										
la	(PLEASE DO I	NOT WRI	TE BELC	W THIS L	INE - CO	NTINUE ON ANO	THER PAGE IF NE	EDED)			
lé		rence	of CDf	RH, Offi	ce of D	evice Evalua	ition (ODE)				
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System/Transducer: PL2226-7.5

Diagnostic Ultrasound Indications for Use Form

	Diagnostic ultrasound imagii nical Application	Mode of Operation									
General	Specific	В	М	PWD	CWD	Color	Amplitude	Combined*	Other**		
(Track 1 only)						Doppler	Doppler	(specify)	(specify)		
Ophthalmic	Ophthalmic										
	Fetal										
	Abdominal										
	Intraoperative (specify)			1							
	Intraoperative (Neuro.)										
	Laparoscopic	· · · · · · · · · · · · · · · · · · ·				7					
	Pediatric										
	Small Organ (specify)										
	Neonatal Cephalic										
	Adult Cephalic										
Fetal Imaging	Trans-rectal										
& Others	Trans-vaginal										
	Trans-urethral										
	Trans-esophageal										
	Muskulo-skeletal										
	Conventional										
	Musculo-skeletal										
	Superficial										
	Intra-luminal	Ei									
i	Other (specify)										
	Cardiac Adult										
	Cardiac Pediatric										
	Cardiac Transesophageal										
Cardiac	Adult										
	Cardiac Transesophageal							İ			
	Pediatric										
	Other (specify)										
Peripheral	Peripheral Vascular										
Vessel	Other (specify)										
l=new indication	on; P=previously cleared by	FDA ur	ider 51	0(k)# K :	971528;	E=added un	der appendix E				
Combination of	f each operating mode, B, N	I, PWD	, CWD	and Co	olor Dop	pler					
	ppler and Harmonic Imaging	i									
dditional Com	ments:							4			
Subscript "a": In	ncludes imaging for guidance	of per	cutane	ous bio	osy or a	odominal org	ans and structi	ires (including	amniocentesis).		
Subscript "b": In	cludes imaging of organs a	nd struc	tures e	exposed	during	surgery (exci	uding neurosu	rgery and lapar	oscopic proceau		
Subscript "c": In	cludes thyroid, parathyroid,	breast,	scrotu	m, peni	s						
Subscript "d": In	cludes thyroid, parathyroid,	breast,	scrotu	m, peni	s and in	aging for gui	dance of biops	у.			
subscript "e": In	cludes imaging for guidance	of trar	srecta	biopsy	•						
	cludes imaging for guidance	of trar	rvagina	Diopsy	<u>/. </u>						
	or pediatric patients.										
ubscript "h": In	cludes imaging for guidance	of trar	srecta	Diopsy	, cryosu	rgery, and br	acnytnerapy.	-1	_L		
	cludes imaging of the biliary	systen	n (pand	reato-b	iliary) ar	nd gastrointes	stinal tract (esc	pnagus, stoma	cn, duodenum, a		
la	rge intestine).	IOT WAIT	E BELO	W THIS I I	NE - CON	TINUE ON ANOT	HER PAGE IF NE	DED)			
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(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

Diagnostic Ultrasound Indications for Use Form

	Diagnostic ultrasound imagir nical Application	<u> </u>					Operation	****	
General	Specific	В	М	PWD	CWD	Color	Amplitude	Combined*	Other**
Track 1 only)						Doppler	Doppler	(specify)	(specify)
Ophthalmic	Ophthalmic		1						
	Fetal							. 1	
•	Abdominal			1					
	Intraoperative (specify)		1	İ					
	Intraoperative (Neuro.)		1	1					
•	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
-4-1 1	Adult Cephalic								
etal Imaging	Trans-rectal								
& Others	Trans-vaginal								
	Trans-urethral								
	Trans-esophageal								
	Muskulo-skeletal								
	Conventional					,			
	Musculo-skeletal								
	Superficial								
	Intra-luminal	Ei							
	Other (specify)								
	Cardiac Adult								
	Cardiac Pediatric						ļ		
	Cardiac Transesophageal				i				
Cardiac	Adult								
	Cardiac Transesophageal								
	Pediatric								
	Other (specify)								
Peripheral	Peripheral Vascular								
Vessel	Other (specify)								
new indication	on; P=previously cleared by	FDA ur	nder 51	0(k)# K	971528:	E=added un	der appendix t	=	
	f each operating mode, B, M		, CWD	and Co	olor nob	pier			
	ppler and Harmonic Imaging								
Iditional Com	ments: ncludes imaging for guidance	of nor	cutono	aue bio	nev of a	ndominal ora	ane and etrijeti	ires (including	amniocentesis)
beerint "b": Ir	ncludes imaging for guidance includes imaging of organs ar	d etru	turas e	VIOS DIO	during	surgery (excl	uding neurosu	rgen, and lanar	osconic proced
becript "c"- Ir	ncludes thyroid, parathyroid,	hreast	scrotu	m neni	s	surgery (exer	daing nearest	igery and rapar	оссорю рассос
becript "d": Ir	ncludes thyroid, parathyroid,	breast	scrotu	m neni	s and in	aging for gui	dance of biops	·V	
	ncludes imaging for guidance					agang tor gar	uarros or prope	J	
	ncludes imaging for guidance								
	or pediatric patients.	. Or trai	Magnic	, blobe	·		· · · · · · · · · · · · · · · · · · ·		
	ncludes imaging for guidance	of tran	srecta	bionsy	Cryosu	rgery, and br	achytherapy.		
bscript "i" In	ncludes imaging of the biliary	syster	n (panc	reato-b	iliary) ar	nd gastrointes	stinal tract (esc	phagus, stoma	ch, duodenum.
	irae intestine).	3,5101	_{(P} aric						. ,
	(PLEASE DO N	OT WRIT	TE BELO	N THIS LI	NE - CON	TINUE ON ANOT	HER PAGE IF NE	DED)	
	Concur	ence o	of CDR	H, Offic	e of De	vice Evaluat	tion (ODE)		
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	-		- / {	<i>JUNE</i> Division	or ≸ign-O	bugal fi) dominal, ENT	<u>-</u>		

Prescription Use (Per 21 CFR 801.109)

	Diagnostic ultrasound imagir					Mode of	Operation		
	nical Application			DWD	CWD	Color	Amplitude	Combined*	Other**
General	Specific	В	М	FWD	CVVD	Doppler	Doppler	(specify)	(specify)
Track 1 only)	(Tracks I & III)					дорр			
Ophthalmic	Ophthalmic						1		
	Fetal								
	Abdominal Intraoperative (specify)								
	Intraoperative (Specify)			 					
	Laparoscopic			 					
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
etal Imaging	Trans-rectal								
& Others	Trans-vaginal								
	Trans-urethral			<u> </u>					
	Trans-esophageal			_					
	Muskulo-skeletal								1
	Conventional			ļ			-		
	Musculo-skeletal					•			
	Superficial			 					
	Intra-luminal			 			-		
	Other (specify)			-			1		
	Cardiac Adult								
	Cardiac Pediatric						1		
Cardiaa	Cardiac Transesophageal								
Cardiac	Adult Cardiac Transesophageal			 					
	Pediatric								
	Other (specify)								
Peripheral	Peripheral Vascular	***************************************	<u> </u>						
Vessel	Other (specify)			1					
Combination of Amplitude Do dditional Com		/I, PWD	o, CWD	, and C	olor Do	opier	nans and struct	ures (including	amniocentesis
ubscript "b": I	ncludes imaging for guidanc ncludes imaging of organs a	nd stru	ctures	expose	d during	surgery (exc	luding neurosu	rgery and lapa	roscopic proced
ubcorint "c": li	ncludes thyroid parathyroid	breast	scroti	ım, pen	is				
ubscript "d": It	ncludes thyroid, parathyroid,	breast	, scroti	ım, pen	is and i	maging for gu	idance of biop	sy.	
ubscript "e": In	ncludes imaging for guidanc	e of tra	nsrecta	al biopsy	<u> </u>				
ubscript "f": In	ncludes imaging for guidanc	e of tra	nvagin	al biops	у				
ubscript "g": F	or pediatric patients.								
ubscript "h": I	ncludes imaging for guidanc	e of tra	nsrecta	al biops	y, cryos	urgery, and b	racnytherapy.	onboque etom	ach duodenum
ubscript "i": I	ncludes imaging of the bilian	y systei	m (pan	creato-l	olliary) a	ina gastronite	estinai tract (es	opnagus, storn	acii, duodeilaiii
la	arge intestine).	YOT WA	TE BEL	W THIS I	INF - CO	NTINUE ON AND	THER PAGE IF NE	EDED)	
	Concili	rence	of CDI	3H. Offi	ce of D	evice Evalua	ation (ODE)		
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	nical Application	ng or fluid flow analysis of the human body as follows: Mode of Operation										
General	Specific	В	М	PWD	CWD	Color	Amplitude	Combined*	Other**			
Track 1 only)						Doppler	Doppler	(specify)	(specify)			
Ophthalmic	Ophthalmic											
Органия	Fetal											
	Abdominal											
	Intraoperative (specify)											
	Intraoperative (Neuro.)											
	Laparoscopic											
	Pediatric											
	Small Organ (specify)											
	Neonatal Cephalic											
atal tananaina	Adult Cephalic											
etal Imaging & Others	Trans-rectal											
& Others	Trans-vaginal						ļ					
	Trans-urethral						<u> </u>					
:	Trans-esophageal											
	Muskulo-skeletal											
	Conventional						<u> </u>	ļ				
	Musculo-skeletal											
	Superficial											
	Intra-luminal	Ei										
	Other (specify)			-								
	Cardiac Adult											
	Cardiac Pediatric						 					
Cardina	Cardiac Transesophageal Adult											
Cardiac	Cardiac Transesophageal											
	Pediatric				l							
	Other (specify)											
Peripheral	Peripheral Vascular											
Vessel	Other (specify)											
=new indication	on; P=previously cleared by	FDA ur	der 51	0(k)# K	971528	; E=added ur	nder appendix I	E				
Combination o	of each operating mode, B, M	1. PWD	, CWD	, and Co	olor Dop	pler						
Amplitude Do	ppler and Harmonic Imaging	,										
dditional Com	ments:											
ubscript "a": Ir	ncludes imaging for guidance	e of per	cutane	ous bio	psy of a	bdominal org	ans and struct	ures (including	amniocentesis).			
ubscript "b": Ir	ncludes imaging of organs at	nd struc	ctures	exposed	during	surgery (exc	uding neurosu	rgery and lapar	oscopic proceau			
ubscript "c": Ir	ncludes thyroid, parathyroid,	breast,	scrotu	ım, peni	s.							
ubscript "d": Ir	ncludes thyroid, parathyroid,	breast,	scrotu	ım, peni	s and ir	naging for gu	idance of biops	sy				
ubscript "e": Ir	ncludes imaging for guidance	e of trar	nsrecta	il biopsy	<u>'. </u>							
	ncludes imaging for guidance	e of trar	nvagina	al biopsy	y		 					
ubscript "g": F	or pediatric patients.			Lhionou		raan, and h	rochuthorany					
ubscript "h": Ir	ncludes imaging for guidance ncludes imaging of the biliary	e of trar	nsrecta	ii biopsy	, cryosi	nd acetrointo	acriyirlerapy.	onhague etomo	ch duodenum			
		/ system	n (pan	creato-u	mary) a	nu gasironite	siliai liaci (esi	opriagus, storic	ich, daoacham,			
18	arge intestine).	OT WRD	TE BELC	W THIS L	INE - COI	TINUE ON ANO	THER PAGE IF NE	EDED)				
	Concur	rence o	of CDF	H, Offic	ce of D	evice Evalua	tion (ODE)					
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